A New Corticoid for Topical Therapy

Fluocinolone Acetonide

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• **Sixty-seven patients with chronic and subacute cutaneous lesions of varying long duration that had previously been resistant to topical use of corticosteroid compounds were treated with a cream containing fluocinolone acetonide. To avoid subjective bias, only two classifications were used in appraising results: "complete clearing of treated lesions" and "not effective."**

Forty-eight patients had complete clearing of the treated area. Results were best in atopic dermatitis, chronic eczematous dermatitis and nummular dermatitis. Granuloma annulare, dyshidrotic dermatitis of the palms and psoriasis were not affected.

In some cases in which there were multiple lesions some of the lesions were treated with fluocinolone acetonide cream and some were treated concurrently with other corticoid ointments or with noncorticoid compounds, either bland or with active ingredients. Fluocinolone was effective in more than twice as many cases as the other agents.

In some of the patients with chronic disease it was possible to greatly reduce or discontinue systemic steroid therapy after fluocinolone acetonide became available.

No untoward effects were observed.

THIS IS A REPORT of the results of the use of fluocinolone acetonide* as a topical treatment of 67 patients with various inflammatory disorders of the skin. The only published report at the time of this writing on the clinical use of this compound is that of Robinson,[3] who found it to be as effective as triamcinolone acetonide and superior to hydrocortisone in the topical therapy of eczematous dermatoses. The chemical make-up of fluocinolone acetonide was discussed in a report by Mills and coworkers.[2]

In the present study the compound was used in a water-miscible vanishing cream base in a concentration of 0.025 per cent. Patients were instructed to apply it lightly three times a day and to massage gently and thoroughly until the cream disappeared.

All the patients were observed in private practice in the office. Many had been observed for several years, and the great majority had chronic recurrent dermatosis in the general category of eczematous dermatitis and had been treated either in the present or past episodes by a variety of currently available methods of therapy, including systemic and topical use of corticosteroids.

CONDITIONS FOR EVALUATION

Evaluation of treatment of acute dermatitis is difficult because so many acute lesions clear spontaneously when the eliciting cause is no longer operating. For this reason, in the beginning of this study we selected only chronic and subacute lesions which had been present for months, and in some instances for years, and which had been resistant to previously applied topical corticosteroids. Furthermore, only two classifications of results were used; one was "very effective with complete clearing of treated lesions" and the other was "not effective" (which included no response or partial response). Use of these absolutes eliminated subjective factors —such as "wishful thinking"—from the appraisal of results.

The relative effectiveness of the compound under discussion was demonstrated in the following ways:

1. It was used on given lesions in patients with multiple lesions and the result was compared with the effectiveness of other standard corticoids used on comparable lesions concurrently.

2. It was used in patients with single chronic lesions in certain cases in which all previously available local and systemic therapy had failed.

3. In patients with multiple lesions, it was used on given lesions, while with other noncorticoid therapy (either bland or other) used concurrently on existing comparable lesions.

CLINICAL RESULTS

Of 67 patients treated (Table 1) 60 had dermatosis of a nature that might be expected to respond to corticoid therapy[1,4]—namely, the general cate-

Presented before the Section on Dermatology and Syphilology at the 90th Annual Session of the California Medical Association, Los Angeles, April 30 to May 3, 1961.

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*Fluocinolone acetonide (6α,9α-difluoro-16α-hydroxy-prednisolone-16, 17 acetonide), kindly supplied, as Synalar® by Syntex Laboratories, Inc., 10 East 40th Street, New York 16.

TABLE 1.—*Results of Treatment of Various Kinds of Dermatosis with Applications of Fluocinolone Acetonide Compound*

Diagnosis	Number of Cases	Results	
		Very Effective (Complete Clearing of Treated Lesions)	Not Effective (Partial or No Response)
Atopic dermatitis ("disseminated neurodermatitis")	16	14	2
Nummular dermatitis	12	11	1
Chronic eczematous dermatitis (unclassified)	14	11	3
Chronic lichenified (dry) dermatitis (lichen simplex or "localized neurodermatitis")	4	2	2
Seborrheic dermatitis	5	5	0
Acute and subacute contact dermatitis	5	4	1
Infectious eczematoid dermatitis (includes otitis externa, 1 case)	2	1	1
Dyshidrotic dermatitis of the palms	2	0	2
Psoriasis	3	0	3
Granuloma annulare	1	0	1
Chronic lupus erythematosus	3	0*	3*

*These three patients showed partial response. Since then, four additional patients have shown prompt and complete clearing. Further experience is needed for valid conclusions.

gory of eczematous dermatitis. Forty-eight of the 60 showed excellent response. In 45 of the patients, the compound under study was compared with one or more of the corticoids currently in clinical use. These included hydrocortisone, triamcinolone and dexamethasone. In 32 of the 45, results with fluocinolone acetonide were better than with the other corticoid; in 11 cases, it was considered equal to the compound with which it was compared (neither having any effect in four of these cases, and both being effective in seven). In two cases of the 45, fluocinolone acetonide was found to be not as effective as the drug with which it was compared—(triamcinolone in one case and hydrocortisone in the other).

The point should be made that what is reported here is the response of individual lesions to treatment, and it is not to be assumed that clearing of lesions means curing of the disease. It is obvious that the clearing of given lesions (in seborrheic dermatitis, for example) does not mean that the disease had been cured. The same principle applies to many cases in this group. Many of the patients have since had new lesions at other sites, which have responded equally well to the same treatment. However, in some patients in this group with chronic disease it has been possible to greatly reduce or completely eliminate the systemic use of steroids since fluocinolone acetonide has become available, topical therapy alone healing new lesions for these patients.

COMPLICATIONS AND REACTIONS

In only one of the 67 patients was there some question of local irritation attributable to the fluocinolone acetonide compound. Results of patch tests with the substance in that patient were negative, and after a rest period of one week the compound was used again, without difficulty. Five patients used the compound almost daily for five months without sign of irritation or sensitization. Nothing that could be interpreted as a systemic effect was noted in any of the patients. No chemical studies of body fluids with this in mind were done, however.

DISCUSSION

Fluocinolone acetonide appears to be a highly effective agent for the topical therapy of inflammatory dermatosis, especially that of eczematous character. It was consistently effective in nummular dermatitis and seborrheic dermatitis, frequently effective in atopic dermatitis and chronic nonspecific eczematous dermatitis; and apparently (on the basis of limited experience) it has a striking effect in acute contact dermatitis.

It was not effective in the treatment of psoriasis, granuloma annulare, or dyshidrotic dermatitis of the palms. Of special interest is its possible effect on chronic cutaneous lupus erythematosus. When adrenal corticosteroids were first introduced for topical use, there were some reports and experiences which indicated that they might be useful in healing individual lesions of chronic cutaneous lupus erythematosus. My experience with three patients indicates that there may be some effect (Table 1).

Seven of the 12 patients who were not benefited by topical therapy with fluocinolone acetonide had complete but temporary subsidence of lesions while receiving systemic steroid therapy.

This compound appears to produce results with topical application that are comparable to those brought about with systemic corticoid therapy. In the present series responses were noted that were

as dramatic as those sometimes observed with systemically administered steroids but rarely occurring with topical therapy available up to the present.

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NOTE: Since the preparation of this paper, the compound has been highly effective in more than 80 per cent of 260 additional patients. When used as an occlusive dressing, lesions of psoriasis responded rapidly. This will be reported in a separate communication.

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